REMARKS

The Examiner's thoughtful attention to the present application is greatly appreciated.

In the Office Action of April 23, 2002, the Examiner indicated that the application did not properly contain an Abstract as required by 37 C.F.R. §1.72. In addition, the Examiner rejected Claims 1 - 6 under 35 U.S.C. §112. Finally, Claims 1 - 6 were rejected under 35 U.S.C. §102.

Reexamination, reconsideration and allowance of Claims 7 - 12 is respectfully requested. Entry of the amendments is also respectfully requested. No new matter is added.

New Claims 7 - 12 are directed to a composition, and a method of using the composition, wherein the composition includes a solvent, a polymer and a hydrophobic group. More particularly, the claim has been clarified, compared to previous Claims 1 - 6, to reflect that a hydrophobic group attaches to a polymer to produce an interaction product wherein the solubility of the polymer is modified to provide a film forming composition. Support for the new claims can most clearly be found on pp. 10 - 25 of the specification.

REJECTION UNDER 35 U.S.C. §112

The Examiner rejected Claims 1 - 6 under 35 U.S.C. §112 contending that the use of the term "other than" was indefinite when Applicant intended to exclude the polymer HPC. Applicant now recognizes that this term is not acceptable to the Patent Office. Accordingly, Applicant has deleted the previous claims, and substituted the term "excluding" to reflect that Applicant's invention excludes HPC as a polymer.[1] Accordingly, this rejection is believed to have been overcome.

The Examiner also rejected Claim 4 as indefinite contending that it was not clear what the interaction agent was interacting with. Applicant believes that it has overcome this rejection by eliminating this term from the claims. Instead, Applicant uses the term "interaction product" which is produced by interacting a polymer with a hydrophobic group. The term "interaction product" is defined throughout the specification, and specifically on p. 10 of the specification.

---

[1] Applicant's investigation has revealed that the term "other than" has not been acceptable within the claims of previous patent applications. Conversely, the term "excluding" is a routinely accepted term appearing in the claims of over 3,600 patents issued in just the last six years.

REJECTION UNDER 35 U.S.C. §102

The Examiner has rejected Claims 1 - 6 under 35 U.S.C. §102 as being anticipated by *Blank* or *Mueller et al.* To overcome these rejections, Applicant has cancelled the previous Claims 1 - 6, and added Claims 7 - 12. The new claims clarify Applicant's invention and are believed allowable over the prior art of record.

Applicant's Claimed Invention

As reflected in the new claims, Applicant's invention is directed to a liquid composition that provides film forming on body tissue. The film forming properties are provided by reacting a polymer, excluding HPC, with a hydrophobic group to alter the solubility of the polymer to produce a water insoluble interaction product. As best described on p. 10 of the specification, Applicant has discovered that hydrophobic modification of polymers is effective to produce liquid compositions for forming films *in situ* upon body tissues. The modified polymer, also referred to as an "interaction product", is water insoluble and is produced by reacting a polymer with a hydrophobic group.

Applicant has specifically excluded HPC from its claimed invention, as a product including HPC was previously sold by Applicant which is described in U.S. Patent Nos. 5,081,157 and 5,081,158. However, it was not disclosed in these references, nor was it known in the prior art, that altering the solubility of a polymer was useful for producing a film

forming composition. It was certainly not known that polymers other than HPC could be modified to form a film forming composition.

Blank (U.S. Patent No. 4,533,540)

Blank describes a film forming composition for administering nitroglycerin to a patient. This reference describes the composition as including a copolymer, a vinylpyrrolidone. However, *Blank* does not describe a composition which includes an interaction product which is produced by reacting a polymer with a hydrophobic group. Moreover, this reference does not describe an interaction product wherein the polymer has an altered solubility as a result of reacting with a hydrophobic group.

Mueller et al. (U.S. Patent No. 4,826,677)

Mueller teaches applying polymer dispersions containing medicines to skin to treat psoriasis. This reference also teaches that the polymer solution polymerizes *in situ* to form a film as the solvent evaporates out of the solution. Further, this reference describes numerous suitable polymers including polyethylene, polyurethane, polyvinylchloride, polyvinyl alcohols, etc. etc.

Again, this reference does not describe a film forming composition which includes an interaction product which is created by attaching a hydrophobic group to a polymer to alter the solubility of the polymer to produce a water insoluble interaction product with film forming properties.

THE REJECTIONS ARE BELIEVED REMOVED BY THE AMENDMENTS TO THE CLAIMS

Applicant's new claims clarify that the present invention is directed to a composition including a solvent and interaction product which will form a film *in situ* on body tissue. Moreover, the interaction product is formed by attaching a hydrophobic group to a polymer to alter the solubility of the polymer to produce a water insoluble interaction product.

As explained above, *Blank*, *Mueller et al.* and the additional prior art references, alone or in combination, do not teach these features.

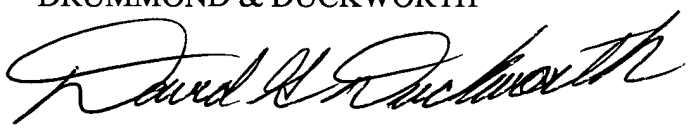
Accordingly, Claims 7 - 12 are believed allowable.

CONCLUSION

It is respectfully requested that Claims 7 - 12 be allowed. It is believed that the claims in this case are in condition for allowance and early notice thereof is respectfully solicited. If there are any remaining issues that need to be resolved, it is respectfully requested that a telephone call be placed to the undersigned.

Respectfully submitted,

DRUMMOND & DUCKWORTH



David G. Duckworth
Registration No. 39,516
Attorney for Applicant
Telephone: (949) 724-1255

VERSION WITH MARKINGS TO SHOW CHANGES MADE
Serial No. 09/509,237

AMENDMENT OF THE CLAIMS

Please cancel Claims 1 - 6 and add the following Claims 7 - 12:

7. The method of forming a film *in situ* upon body tissue comprising:

providing a liquid composition comprising,

1) a volatile solvent; and

2) a polymer, excluding hydroxypropylcelllulose, which will attach to a hydrophobic group, and

3) a hydrophobic group;

modifying the solubility of the polymer in the liquid composition by attaching the hydrophobic group to the polymer to produce a water insoluble interaction product;

applying the liquid composition to body tissue; unclear

evaporating the solvent from the liquid composition *in situ*; and

forming a film which adheres to body tissue.

VERSION WITH MARKINGS TO SHOW CHANGES MADE
Serial No. 09/509,237

8. The method of forming a film *in situ* upon body tissue of claim 7 wherein the liquid composition includes a medicament.

9. The method of forming a film *in situ* upon body tissue of claim 7 wherein the polymer is selected from the group consisting of carboxymethylcellulose, poly(vinyl alcohol-co-vinyl acetate), polyiminodiacetamide, and hydroxyethylcellulose,

10. A composition which forms a medicated film *in situ* upon boy body tissue comprising:

a volatile solvent; and

an interaction product which is soluble in said solvent but insoluble in body fluids, the interaction product produced by reacting a polymer, excluding hydroxypropylcellulose, with a hydrophobic group, wherein the hydrophobic group attaches to the polymer to alter the solubility of the polymer to produce a water insoluble interaction product;

said interaction product forming a film which adheres to body tissue upon evaporation of said solvent.

VERSION WITH MARKINGS TO SHOW CHANGES MADE
Serial No. 09/509,237

11. The composition which forms a medicated film *in situ* upon boy tissue of claim 10 further comprising a medicament.

12. The composition which forms a medicated film *in situ* upon ~~boy~~ body tissue of claim 10 wherein the polymer is selected from the group consisting of carboxymethylcellulose, poly(vinyl alcohol-co-vinyl acetate), polyiminodiacetamide, and hydroxyethylcellulose.

VERSION WITH MARKINGS TO SHOW CHANGES MADE
Serial No. 09/509,237

ABSTRACT

Methods and compositions for forming protective and/or medicated films on body tissue. Liquid compositions contain a hydrophobically modified polymer, other than an esterified lower-hydroxyalkyl-subsituted cellulose, suspended or dissolved in a solvent. The modified polymer is soluble in the solvent but insoluble in body fluids. The compositions may optionally contain a separate medicinal component, i.e., one which is present in addition to any medications, if any, present in the solvent, in the modified polymer and in any other additive components such as flavors, skin penetrants, preservatives, other solvents for the additives, etc. A protective and/or medicated film is formed *in situ* upon body tissue by applying the liquid composition to the tissue and separating the solvent from the composition, e.g., by vaporization.